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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/817,003	03/22/2001	David M. Sabatini	50347/002004	5682
21559	7590	08/28/2008	EXAMINER	
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110		KAUSHAL, SUMESH		
		ART UNIT		PAPER NUMBER
		1633		
		NOTIFICATION DATE		DELIVERY MODE
		08/28/2008		ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

[patentadministrator@clarkelbing.com](mailto:patentadministrator@clarkelbing.com)

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/817,003	SABATINI, DAVID M.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Sumesh Kaushal	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 3/24/08.
- 2a) This action is **FINAL**.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 160-177 and 237-271 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 160-177 and 237-271 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ .  | 6) <input type="checkbox"/> Other: _____ .                        |

## DETAILED ACTION

Applicant's response filed on 03/24/08 has been acknowledged and fully considered.

*Claims 253-271 are newly filed.*

*Claims 160 is amended.*

*Claims 160-177 and 237-271 are pending and are examined in this office action.*

*The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The references cited herein are of record in a prior Office action.*

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 160-169, 172-175, 178-248, 251, 253-254, 257, 259-260, 263, 265-266, 269 and 271 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Palsson (US 5811274, 1998).

The instant invention as claimed read on a product by process, wherein the final product comprises an array of transfected cells in a culture media.

Palsson teaches methods, compositions and apparatus for cell transfection. The cited art teaches a method of transfecting target cells with particles comprising the steps of: a) depositing the particles on a cell growth support in an amount effective for increasing the transfection efficiency of target cells compared to that achieved by particles suspended in liquid; and b) contacting the target cells with the particle-loaded cell growth support. The cited art further teaches that the particles are selected from viral particles, RNA or DNA particles, liposome, spheroplast, red blood cell ghost, DNA-calcium phosphate precipitate or DNA-DEAE Dextran carriers. The cited art further teaches that target cells are animal cells or human cells. The cited art further teaches that the cell growth support is a filter, membrane filter, cell culture surface, or tissue engineering material, wherein the cell growth support is a cell culture surface. The cited art further teaches that the cell growth support contains a polycation (polybrene, protamine sulfate) in an amount effective for attachment of the particles to the cell growth support. The cited art further teaches that the depositing the particles on the cell growth support is achieved by filtering or adsorbing the particles onto the cell growth support (see col. 15 and 16).

The cited art further teaches that the cell culture surface is a solid surface to which particles can be localized and on which target cells grown. The cited art teaches that the cell culture surface includes those dishes, plates, flasks, bottles and hollow-fiber cell culture systems produced by various manufacturers for growing cells including COSTAR, NUNC and FALCON (see col. 5-6, especially lines 38-). Thus given the broadest reasonable interpretation the cited art clearly anticipates the invention as claimed.

***Claim Rejections - 35 USC § 103***

Claims 170-171, 176-177, 249-250, 252, 255-256, 258, 261-262, 264, 267-268, 270 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palsson (US

5811274, 1998) as applied to claims 160-169, 172-175, 178-248, 251, 253-254, 257, 259-260, 263, 265-266, 269 and 271 above, and further in view of Montgomery et al (PNAS 95(26): 15502-7, 1998, ref of record) and Fire et al (US 6506559, 2003, ref of record).

Palsson is relied upon as described in rejection above. However, Palsson does not teach the use double-stranded RNA molecule or nucleic acid molecule having a modified base or backbone.

Montgomery teaches the double-stranded RNA mediated genetic interference in C.elegans. The cited art teaches a nucleic acid molecule, which encodes double-stranded RNA for RNAi experiments (page 15502, col2. para.2). The cited art teaches gene-specific probes for insitu hybridization, wherein the probe comprises Digoxigenin (DIG)-labeled single stranded DNA probe (page 15503, co1.2, para. 3).

Fire et al teaches a method to inhibit expression of a target gene in a cell in vitro comprising introduction of a ribonucleic acid (double-stranded RNA molecule) into the cell in an amount sufficient to inhibit expression of the target gene. The cited art further teaches that the solutions containing duplex RNAs that are capable of inhibiting the different expressed genes can be placed into individual wells positioned on a micro titer plate as an ordered array, and intact cells/organisms in each well can be assayed for any changes or modifications in behavior or development due to inhibition of target gene activity. The cited art further teaches that the function of the target gene can be assayed from the effects it has on the cell/organism when gene activity is inhibited (see col. 12 lines 46-; col. 26-28 and col. 11-12).

Thus it would have been obvious to one ordinary skill in the art at the time of filing to modify the invention of Palsson in view of Montgomery or Fire by substituting the nucleic acid molecules with a double-stranded RNA molecule, a nucleic acid molecule that interfere with the function of an endogenous gene or a nucleic acid molecule having a modified base or backbone. One would have been motivated to incorporate such a modification to inhibit the expression of a gene of interest. One would have a reasonable expectation of success, since affixing the nucleic acid sequences on various types of tissue culture supports and transfection of cells using the

affixed nucleic acid has been routine in the art at the time the instant invention was made. Thus the invention as claimed is *prima facie* obvious in view of cited prior art of record.

***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal whose telephone number is 571-272-0769. The examiner can normally be reached on Mon-Fri. from 9AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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